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K092567

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Attachment 5 - 510K Summary

510(K) summary
(As Required by Section 807.92 (c))

Name:	Unicare Biomedical, Inc.
Address:	22971 Triton Way, Unit B, Laguna Hills, CA 92653
Contact:	Stan Yang, 949-643-6707
Date:	August 16, 2009

Trade Name:	Unigraft
Common Name:	Synthetic bone graft material
Classification Name:	Endosseous implant for bone filling and augmentation
Device Classification:	II

Device Description

Unigraft is a synthetic bioactive glass that is intended for use in the repair of oral/maxillofacial and dental intraosseous defects. The bioactive glass granules are supplied sterile in a polyolefin vial within a sealed pouch.

Predicate Devices

The Unigraft device is substantially equivalent to devices currently in US commercial distribution, which are classified as endosseous implants for bone filling and augmentation. Examples of such products include Unigraft®, PerioGlas® and Osteograf®. These products are made of bioceramic materials with similar performance.

Intended Use

Unigraft® is indicated for the repair of dental intraosseous and oral/maxillofacial defects, including: augmentation of the alveolar ridge, filling of infrabony periodontal defects, filling of extraction sockets to enhance preservation of the alveolar ridge, elevation of the maxillary sinus floor, filling of defects after cystectomy, apicoectomy and root resection, filling of periodontal and peri-implant defects in conjunction with products intended for GTR and GBR procedures, and filling of maxillofacial osseous cavities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 25 2009

Mr. Stan Yang
Vice President
Unicare Biomedical, Incorporated
22971 Triton Way, Unit B
Laguna Hills, California 92653

Re: K092567
Trade/Device Name: Unigraft®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: November 18, 2009
Received: November 24, 2009

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092567

Attachment 7 - Indications For Use Statement

510K Number: _____

Device Name: Unigraft®

Indications for Use:

Unigraft® is indicated for the repair of dental intraosseous and oral/maxillofacial defects, including: augmentation of the alveolar ridge, filling of infrabony periodontal defects, filling of extraction sockets to enhance preservation of the alveolar ridge, elevation of the maxillary sinus floor, filling of defects after cystectomy, apicoectomy and root resection, filling of periodontal and peri-implant defects in conjunction with products intended for GTR and GBR procedures, and filling of maxillofacial osseous cavities

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X____ or Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nicholas Nolan for Kevin Mulhy

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092567